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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,425

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EXAMINER

FORMAN, BETTY J

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,425	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4,6,7 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4,6,7 and 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 14 January 2010 in which claims 2, 4, 6, 12, 14 and 15 were amended and claims 1, 3, 5, 8-11 and 16-25 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 July 2009 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 2, 4, 6, 7, 12-15 are under prosecution.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2, 4, 6, 7 and 12-15 are rejected under 35 U.S.C. 103(a) as obvious over Krutzik (U.S. Patent No. 7,141,416, filed 12 July 2002) in view of Sandstrom (U.S. Patent No. 6,545,758, issued 8 April 2003) and Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding Claim 2, Krutzik teaches a biochip readout device comprising a rotatable biochip cartridge (#110) having a biochip installed on the disc (e.g. microarray

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#147, Fig. 15, Column 13, lines 3-20). Krutzik further teaches a light reception means for receiving beam from the disc (i.e. focusing and tracking via bottom detector #157) having a light source scanning the disc (#150), a focusing/tracking control using the light reception means (Column 13, lines 21-52), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 14, lines 21-44 and Column 15, lines 57-64), an optical pick-up device for analyzing the biosignals from the biochip (top detector #158, Column 12, lines 21-52, Fig. 16). Krutzik teaches the device comprises a system and output controlling unit for monitoring analysis information, processing the signal (#166/168, Column 13, lines 46-52). Krutzik further teaches the device compares signals to known and/or reference analytes (Column 17, lines 8-12 and 37-41) and further that the device provides for automated analysis of physiological disorders (Column 1, lines 66-Column 2, line 8). All of this clearly suggests the device is a diagnostic device for monitoring and comparing database information.

Furthermore, computerized diagnostics was well known and routinely practiced in the art at the time the invention was made as taught by Sandstrom (Column 4, line 53-Column 5, line 34). Sandstrom teaches a device wherein all elements of biochip construction, use and analysis are provided within the computerized system whereby the information is efficiently processed, stored and/or interpreted (Column 5, lines 61-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diagnostic analysis of Sandstrom to the device of Krutzik. One of ordinary skill in the art would have been motivated to do so, with a

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reasonable expectation of success, for the well known benefit of efficient processing and interpreting as taught by Sandstrom (Column 5, lines 61-67).

Krutzik further teaches the device further comprising an optical recording unit (analyzer #168) for recording signals in response to trigger mechanism (#126/160) and output unit for producing analysis information (Column 3, lines 25-67) wherein the trigger mechanism prompts the system to data collection when the trigger marking are detected thereby selecting for readout vs general scanning (Column 13, lines 35-52) wherein the biodisc is attached to the cartridge using an adhesive (#118, Column 7, lines 21-24) wherein the disc is formed by spotting biocells within a groove (Column 19, lines 12-31 and Column 25, lines 42-47) wherein the reflective film is selectively reflect allowing some light to pass and some light to be reflected (Column 15, lines 22-29, Fig. 20).

Krutzik further teaches the device wherein the cartridge is a disc in which depressed portions are formed (Fig. 17-18) wherein the biodisc (#140) is installed in depressed portions (Fig. 15, 17-18) wherein the biochip includes an adhesive layer (#118, Column 7, lines 21-24). Figure 15 provides a view of the capture zone (#140) in microarray format (#147). Figures 17-18 provide a side view of the biodisc wherein the capture zone (#140) is clearly positioned in a groove of the fluidic circuit. Additionally, Wang teaches a biodisc similar to that of Krutzik wherein the arrays are prepared separately and then positioned on the biodisc (Column 14, lines 35-59).

Krutzik further teaches the cartridge wherein the adhesive member provides a fluidic circuit (Column 7, lines 36-39), but does not specifically teach that the biochip

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cannot be separated when the disc is rotated. However, sealed cartridges providing controlled assay environments were well known as taught by Sandstrom (Column 32, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of Krutzik to perform the arrays as taught by Wang and subsequently seal the cartridge while in use as taught by Sandstrom. One of ordinary skill in the art would have been motivated to do so for the well known benefits of controlled assay environments as desired in the art (Sandstrom, Column 32, lines 40-47).

Regarding Claim 4, Krutzik teaches the device wherein the signal generation unit scans the biochip cartridge with light in response to control unit (via trigger mechanism) using a single light source while controlling focusing and tracking (Column 13, lines 21-52 and Column s 14-15).

Regarding Claim 6, Krutzik teaches the device wherein a fluorescent signal is detected (Column 2, lines 60-63) and compared to known reference or concentration (Column 17, lines 9-12 and 37-41) and further teaches the device monitors and processes information (Column 3, line 25-Column 4, line 12) thereby teaches the structural elements required by the claim.

Regarding Claim 7, Krutzik teaches the device detects fluorescence, but is silent regarding a fluorescence filter. However, Sandstrom teaches the device further comprising an emissions filter and detector (i.e. collection optics Column 34, lines 47-65).

Regarding Claim 12-14, Krutzik and Sandstrom teach the elements of Claim 7 as discussed above. Krutzik further teaches the device wherein a pin-spotter is used for patterning (Column 25, line 45) and Sandstrom also teaches a pin-spotter used for patterning (Column 23, lines 57-64). The references do not teach a servo device for rotating the substrate at a predetermined speed while spotting and a controlled unit for controlling the servo device. However, servo devices providing controlled rotation while spotting a pattern onto the substrate was known in the art as taught by Wang.

Wang teaches a biochip readout device similar to that of Krutzik, the device comprising a rotatable biochip cartridge (#74) having a biochip installed on the disc (e.g. segment #70, Fig. 5, Column 14, lines 35-44). Wang further teaches a light reception means for receiving beam from the disc (i.e. focusing, tracking & header detector #134/136) having a light source scanning the disc (#102, Column 11, lines 40-67), a focusing/tracking control using the light reception means (Column 15, lines 28-45), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 15, lines 32-36), an optical pick-up device for analyzing the biosignals from the biochip (#124, Column 15, lines 45-58, Fig. 7) and a system and output controlling unit for monitoring analysis information, processing the signal (Column 17, lines 13-55).

Wang further teaches the device comprising a patterning device (printer) comprising a servo device for rotating the disc (raster scanner) and a printer for patterning the biocell on the substrate and a controller (servooptics) for controlling the entire system for rotation and printing (Column 12, lines 33-43 and Column 17, lines 24-47).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the controlled servo device of Wang to the device of Krutzik to thereby provide for patterned spotting using controlled rotation at constant speed to provide desired pattern on the substrate as taught by Wang (Column 12, lines 33-43). Wang teaches that using the same elements to align the biodisc for printing and detecting the array precisely and rapidly aligns the biochip (Column 12, lines 33-43). Therefore, one of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of rapid positioning as taught by Wang (Column 12, lines 33-43).

Regarding Claim 15, Sandstrom further teaches the device further comprising a communication device for transmitting analysis and signal information to a readout device (Column 4, lines 53-67).

### ***Response to Arguments***

4. Applicant argues that Krutzik does not teach one or more depressed regions wherein biochip formed by spotting bio-cells is installed. Applicant acknowledges the fluidic circuits and target zones of Krutzik but asserts that the target zones differ from the instantly claimed structure having depressed regions to receive biochips. The argument has been considered but is not found sufficient to overcome the rejection set forth above.

Krutzik specifically teaches the device wherein the cartridge is a disc in which depressed portions are formed (Fig. 17-18) wherein the target zones (#140) are installed within depressed portions (Fig. 15, 17-18 and Column 13). Figure 15 provides

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a view of the capture zone (#140) in microarray format (#147). Figures 17-18 provide a side view of the target zone (#140) which is clearly positioned in a groove of the fluidic circuit. While Kurtzik is silent regarding the installation of the target zone, the method of making a device does not define over a device made by another method.

The courts have stated that “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Furthermore, Wang teaches a biodisc similar to that of Krutzik wherein the arrays are prepared separately and then positioned on the biodisc (Column 14, lines 35-59).

Sandstrom teaches sealed cartridges having installed biochips thereby providing controlled assay environments (Column 32, lines 40-47).

Applicant argues that Wang does not cure the deficiencies of Krutzik because Wang does not teach grooves or depressed portions for the biochips. The argument has been considered. However, Krutzik clearly teaches the arrayed target zones within the grooves of the fluidic circuit. The only element missing from Krutzik is a teaching of how the arrayed target zones are placed into the grooves. Wang teaches installation of preformed arrays onto a biodisc wherein the installation is preformed using “any convenient means” and wherein the preformed arrays provides “greater flexibility in

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assaying samples while still providing the rapidity and accuracy” (Column 14, lines 35-59). Hence, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the target zones of Krutzik for installation within the grooves of the fluidic circuit. The artisan would have been motivated to do so for the expected benefit of "greater flexibility in assaying samples while still providing the rapidity and accuracy” as taught by Wang (Column 14, lines 55-59).

It is maintained that the prior art teaches all the elements of the instantly claimed invention.

### ***Conclusion***

5. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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